PEARSON, J.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

JANE OLSZESKI, Plaintiff, v. ETHICON WOMEN'S HEALTH AND UROLOGY, *et al.*, Defendants.	)	CASE NO. 5:19CV1787 JUDGE BENITA Y. PEARSON **MEMORANDUM OF OPINION AND ORDER (*GENERAL OPINIONS*)** [Resolving ECF Nos. 135, 137, and 143]

Pending are Plaintiff's and Defendants Ethicon, Inc. and Johnson & Johnson's motions to strike report and/or exclude testimony of an expert witness (general opinions) (ECF Nos. 135, 137, and 143). The Court has been advised, having reviewed the record, the parties' briefs, and the applicable law.

I. Background

The background set forth in the Memorandum of Opinion and Order (ECF No. 301) is incorporated by reference herein.

II.

The Federal Rules of Evidence, and specifically Rule 702, "assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrill Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). Rule 702 governs the admissibility of expert testimony and codifies the Supreme Court's holdings in *Daubert* and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999). Expert testimony is

admissible only if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the expert has reliably applied the principles and methods to the facts of the case. Fed. R. Evid. 702. The proponent of the expert testimony has the burden of establishing by a preponderance of the evidence that the proposed testimony satisfies those standards. *See* Fed. R. Evid. 702 advisory committee's note (2000); *Daubert*, 509 U.S. at 592 n.10. Expert testimony is not admissible "is the exception rather than the rule." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 530 (6th Cir. 2008) (quoting Fed. R. Evid. 702 advisory committee's note (2000)).

Furthermore, *Daubert* analysis includes consideration of Fed. R. Evid. 403. *Daubert*, 509 U.S. at 595. Therefore, courts in the Sixth Circuit employ a four prong test to determine the admissibility of expert opinions: "(1) that the witness, a qualified expert, (2) was testifying to a proper subject, (3) which conformed to a generally accepted explanatory theory, and (4) the probative value of the testimony outweighed its prejudicial effect." *United States v. Smithers*, 212 F.3d 306, 312 (6th Cir. 2000) (citing *United States v. Green*, 548 F.2d 1261 (6th Cir.1977)).

III. ECF No. 137 - Shelby Thames, Ph.D.

Dr. Thames is a polymer chemist with a Ph.D. in organic chemistry and Defendants' material scientist in the case at bar. He served as a general expert during the MDL, in which he offered several opinions in defense of Ethicon's PROLENE-based meshes used by Ethicon to manufacture its SUI devices, including the TVT-O device that allegedly injured Plaintiff. He opines that it does not degrade after implantation into the human body. ECF No. 137-16 is his General Report. Dr. Thames's general opinion is that "Ethicon's Prolene material used in its

mesh products does not undergo meaningful or harmful degradation *in vivo*." ECF No. 137-16 at PageID #: [6]. ECF No. 137-19 is his case-specific report. The motion requests that the Court limit Dr. Thames' general and case-specific opinions. Sections A (the PROLENE used in Defendants' SUI mesh products undergoes *in vivo* degradation) and C (Dr. Thames cannot determine PROLENE's "toughness" from the tensile testing data collected from year 7 of Dan Burkley's dog study) of that motion are challenges to general opinions of Dr. Thames. Only these general portions will be addressed in this opinion.

A.

According to Plaintiff, Defendants have already admitted under oath through their 30(b)(6) corporate witness in the MDL, Dr. Thomas Barbolt, that the PROLENE used in their SUI mesh products undergoes *in vivo* degradation. Dr. Barbolt testified as follows at his trial deposition:

> Q. . . . Is it Ethicon's position that the antioxidants in the polypropylene Prolene fibers in TVT can leach from the fibers?
>
> MR. THOMAS: Object to the form of the question.
>
> THE WITNESS: Yes.
>
> * * *
>
> Q. And could you explain to the ladies and gentlemen of the jury what we mean by "leach"?
>
> A. Leaching means the movement of substances from an implant into the surrounding tissue.
>
> * * *

Q. So you would agree as a spokesperson -- as a 30(b)(6) person for Ethicon that the surface of polymer fibers, including the polypropylene fibers in TVT, can crack?

MR. THOMAS: Object to the form of the question.

THE WITNESS: Yes.

* * *

Q. Despite the antioxidants being added to the Prolene sutures, in two of the Prolene sutures in the study, the surface layer was cracked, correct?

MR. THOMAS: Object to the form of the question.

THE WITNESS: Two revealed cracking, yes.

BY MR. THORNBURGH:

Q. And you aren't suggesting to the ladies and gentlemen of the jury that those cracks were anything other than the Prolene polypropylene, are you?

A. No, I am not suggesting that, and that's not reflected in this report.

Q. You would agree that the surface layer that's cracked here is the polypropylene surface layer, correct?

MR. THOMAS: Object to the form of the question.

THE WITNESS: In reading the report, it says that -- *that's what I would conclude*.

* * *

Q. *And that's Ethicon's position as you -- as the spokesperson for Ethicon, it's Ethicon's position that degradation, surface degradation, can occur, correct?*

MR. THOMAS: Object to the form of the question.

THE WITNESS: *Yes.*

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BY MR. THORNBURGH:

Q. And this was known well in advance of this statement that the material is not absorbed, nor is it subject to degradation, correct?

A. Yes. This is from 1992.

Deposition of Thomas A. Barbolt, Ph.D. (ECF No. 137-15) at PageID #: [360:20-25, 361:2-6, 385:14-20, 396:2-23, 409:2-13] (emphasis added). Plaintiff contends this binding testimony shows that PROLENE undergoes *in vivo* surface degradation and that Defendants knew this several years prior to disseminating misinformation to physicians in its labeling that erroneously claims that PROLENE does not degrade. Plaintiff argues Defendants should be precluded from providing new evidence or testimony through Dr. Thames that contradicts the testimony provided by the designated 30(b)(6) corporate witness. *See Rainey v. American Forest & Paper Ass'n. Inc.*, 26 F. Supp.2d 82, 94 (D.D.C. 1998).

In response, Defendants argue Dr. Thames's opinions are not barred by the Fed. R Civ. P. 30(b)(6) deposition testimony of Dr. Barbolt. According to Defendants, a full reading of Dr. Barbolt's testimony shows he does not admit Prolene degrades *in vivo*, and instead refers to subjective observations of surface cracking having no significance to the claims of degradation. He explains these observations are not the same as objective assessments necessary to establish Prolene meaningfully degrades *in vivo*. For example:

Q. Are you telling the ladies and gentlemen of the jury that when the outer surface of the polypropylene fibers crack and peel away from the surface, that that is not degradation?

MR. THOMAS: Object to the form of the question.

> THE WITNESS: I am telling listeners that the key endpoint of adverse effects of degradation are molecular weight and tensile strength, both quantitative measures, not subjective assessments of surface changes, but quantitative measures that hold great weight and suggest that there's no degradation to the Prolene fiber in terms that are significant.

ECF No. 137-15 at PageID #: [373:24-374:12]; *see also* [448:19-449:16] (explaining that a study reported "no evidence of degradation that's meaningful."). Defendants assert the opinions of Dr. Thames are consistent with Dr. Barbolt's testimony, and simply go a step further and shows that the cracked material is protein and not degraded mesh. *See, e.g.,* ECF No. 137-16 at PageID #: [10] ("there are those who allege Prolene's structural changes *in vivo* are sufficient to affect property/device function loss. However, this tenet is not founded on factual, reliable and repeatable scientific data of which I am aware. It is my opinion, supported by extensive and repeatable experimental data, that such proponents have historically, and erroneously, identified adsorbed protein coatings on the implant surface as polypropylene; they are mistaken.").

This prong of the motion is denied. *See Pitlyk v. Ethicon, Inc.*, No. 20-cv-00886-SRB, slip op. at 2 (E.D. Mo. July 7, 2021) ("The motion is DENIED insofar as the Court finds that Defendant Ethicon is not bound by the admissions of its Federal Rule of Civil Procedure 30(b)(6) witness Dr. Thomas Barbolt, and DENIED insofar as the Court will not exclude Dr. Thames's opinions that contradict the testimony of Dr. Thomas Barbolt."); *Mason v. Ethicon, Inc.*, No. 6:20-cv-1078-RBD-DCI, 2021 WL 2580165, at *3 (M.D. Fla. June 10, 2021) ("Assuming Dr. Thames' testimony contradicts the testimony of Defendants' 30(b)(6) witness, this is an insufficient basis to preclude Dr. Thames' opinion.").

B.

Next, Plaintiff argues Dr. Thames cannot determine PROLENE's "toughness" from the tensile testing data collected from year 7 of the dog study.[1] Dr. Thames opines "[t]aken in totality, Burkley's physical property/toughness data validates toughness 'improvement' after the initial implantation, and confirms no meaningful loss in molecular weight." ECF No. 137-16 at PageID #: [9].

According to Defendants, Dr. Thames has a scientific basis for finding that the dog study showed "toughness" in Prolene increased and that demonstrates no degradation. Defendants maintain Plaintiff's argument is virtually identical to the argument in Plaintiffs' Wave 2 Motion in the MDL. In adopting its Wave 1 Thames Order, the MDL rejected this argument and denied plaintiffs' motion, finding that Dr. Thames "used a systematic method to plot data collected in the dog study on strength and elongation that could reasonably be said to relate to toughness." *In re Ethicon, Inc.*, MDL No. 2327, 2016 WL 4608160, at *3 (S.D.W.Va. Sept. 2, 2016).

This prong of the motion is denied. The Court will follow the MDL court's ruling.

IV. ECF No. 135 - Bruce Rosenzweig, M.D.

Dr. Rosenzweig is a pelvic surgeon and board-certified urogynecologist. ECF No. 135-2 is his General Report. ECF No. 135-3 is his case-specific report. The motion requests that the

[1] Plaintiff offers no testing or relevant scientific support for her claim that Dr. Thames's opinions are not reliable. Plaintiffs' general expert Scott Guelcher, Ph.D. testified that toughness cannot be determined from "Figure 6. Plot of Burkley 7 Year Dog Study Data" in Dr.Thames' report. *See* ECF No. 137 at PageID #: 14557 n. 36. Plaintiff subsequently filed a Notice of Withdrawal of Plaintiff's Expert Scott A. Guelcher (ECF No. 205).

Court limit his general and case-specific opinions. Sections II.A. (offering opinions that the MDL court has excluded), II.F. (criticizing Ethicon's collection and reporting of adverse events), and II.H. (testifying about the propylene resin MSDS sheet) of the motion are challenges to Dr. Rosenzweig's general opinions. Only these general portions will be addressed in this opinion.

A.

Defendants argue the Court should preclude Rosenzweig from offering opinions that the MDL court has excluded. Specifically, Rosenzweig should be precluded from opining on (1) Defendants' level of testing of TVT-O, (2) the level of training that Defendants provided to physicians concerning the use of TVT-O (and the level of funding for such training), and (3) the Material Safety Data Sheet ("MSDS") for raw polypropylene. In addition, Rosenzweig should be precluded from (4) providing a narrative summary of corporate documents, including providing marketing opinions and (5) offering legal conclusions and speculating about Defendants state of mind and corporate conduct.

In response, Plaintiff declares "Dr. Rosenzweig will not be offering 'legal conclusion' testimony nor testimony concerning the adequacy of Ethicon's testing, Ethicon's 'state of mind,' or Ethicon's 'corporate conduct' (from the standpoint of corporate state of mind/corporate ethics)." ECF No. 155 at PageID #: [2]. Therefore, this part of the motion is denied as moot.

Rosenzweig will be permitted to opine as to (1) the contents of corporate documents of Defendants he has reviewed, (2) the level of training Defendants provided to physicians regarding the use of the TVT-O and the marketing materials Defendants provided the medical community, and (3) the extent to which Defendants adequately trained physicians on the risks

and complications of the TVT-O. Such testimony will assist the jury in determining the ultimate issues in the case at bar. Objections to Rosenzweig providing an "impermissible factual narrative" may be considered at trial with the benefit of context. *See In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 4072058, at *8 n.9 (N.D. Ohio Aug. 29, 2019). Rosenzweig, however, will not be permitted to offer his opinion about his "review[ ] [of] corporate documents showing that Ethicon cut funding for professional trainings which [he] says 'contrasted' with Ethicon's corporate credo." *Huskey v. Ethicon, Inc.*, 29 F. Supp.3d 691, 706 (S.D.W. Va. 2014). Therefore, this part of the motion is granted in part and denied in part.

Consistent with the Court's ruling on Defendants' Motion *in Limine* No. 7 (ECF No. 231), the Court will defer ruling on whether Rosenzweig will be permitted to testify about the MSDS for raw polypropylene until the time of trial. *See* Transcript of Proceedings (ECF No. 282) at PageID #: [98-100].

B.

According to Defendants, the Court should preclude Rosenzweig from criticizing Defendants' collection and reporting of adverse events. According to Rosenzweig, "Ethicon's collection and reporting of adverse events and complications to physicians and patients was incomplete, inaccurate and misleading." ECF No. 135-2 at PageID #: [100]; *see also* [97-101].

In response, Plaintiff states "Dr. Rosenzweig will not offer any opinions at trial regarding Ethicon's *collection* of adverse event reports nor Ethicon's compliance with FDA adverse event reporting regulations." ECF No. 155 at PageID #: [9] (emphasis in original). Therefore, this part of the motion is denied as moot.

Plaintiff argues that Dr. Rosenzweig should be permitted to provide opinions concerning the extent to which Ethicon's *reporting* of adverse events and complications to patients, physicians, and the medical community was incomplete, inaccurate, and misleading because such testimony would assist the trier of fact in evaluating Plaintiff's failure to warn claims. The Court agrees. *See* Ohio Rev. Code § 2307.76.

Defendants cite *Heinrich v. Ethicon, Inc.*, No. 2:20-cv-00166-APG-VCF, 2021 WL 2290996 (D. Nev. June 4, 2021), in support of this part of ECF No. 135. In the motion in *Heinrich*, the defendants initially argued that Dr. Rosenzweig should not be allowed to testify that Ethicon's collection and report of adverse events and complications was incomplete, inaccurate, and misleading. In their reply, however, the defendants narrowed their request to exclude only his opinion that Ethicon's collection of adverse events and complications was incomplete, inaccurate, or misleading. The court granted that portion of the defendants' motion as narrowed in its reply brief. *Id.* at *4. "Dr. Rosenzweig therefore [was] not precluded from opining about whether Ethicon adequately reported (as opposed to collected) adverse events and complications." *Id.* at *4 n. 1.

Therefore, this part of the motion is denied. Plaintiff will not, however, be permitted to improperly use Rosenzweig as a "conduit for corporate information." *See In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 8788207, at *7 (S.D.W.Va. Aug. 26, 2016).

C.

Finally, Defendants argue the Court should not allow Rosenzweig to testify about the polypropylene resin Material Safety Data Sheet ("MSDS"). Rosenzweig accuses Defendants of failing to warn of information contained in the MSDS for polypropylene resin that is used in the device's mesh. ECF No. 135-2 at PageID #: [61]. When most recently weighing in on Rosenzweig's qualifications to provide such opinions, Judge Goodwin found as follows in the Boston Scientific MDL:

> . . . BSC objects to Dr. Rosenzweig's opinion that the Advantage, Advantage Fit, and Lynx should not be used in the body because the manufacturer of the raw polypropylene has included in its MSDS a medical application caution stating that the material should not be permanently implanted in the body. BSC claims that this opinion is irrelevant.
>
> Dr. Rosenzweig's opinion about the MSDS enters subject matters about which he is not qualified to testify. Specifically, Dr. Rosenzweig concludes that BSC did not perform the necessary testing that it should have to investigate the MSDS warning. As explained above, Dr. Rosenzweig lacks the experience and knowledge necessary to opine on what testing a manufacturer should perform on his products. These opinions, therefore, are **EXCLUDED**. . . .

In re Boston Scientific Corp. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2326, 2018 WL 8054292, at *3 (S.D.W.Va. May 30, 2018) (bold in original).

In response, Plaintiff contends Rosenzweig's opinions concerning the polypropylene resin in Ethicon's MSDS sheet largely relate to what physicians (such as himself, a practicing urogynecologist) should have been warned about. Plaintiff cites Judge Goodwin's prior ruling in the Ethicon MDL. *In re Ethicon Inc.*, 2016 WL 8788207, at *4 ("Ethicon also argues that Dr. Rosenzweig is unqualified to offer opinions based on the MSDS because Dr. Rosenzweig does not know how the MSDS was prepared. I disagree. A urogynecologist does not need to be an

expert in crafting MSDS warnings to use the substance of such warnings in forming opinions about how mesh reacts in the human body. Accordingly, Ethicon's Motion is **DENIED** on this point.") (emphasis in original); *see also* *Wood v. American Med. Sys. Inc.*, No. 1:20-cv-00441-DDD-KLM, 2021 WL 1178547, at *11 (D.Colo. March 26, 2021) (finding Rosenzweig's MSDS opinions are admissible and that discrepancies in the evidence is something that could be pursued in cross examination rather than requiring exclusion).

Consistent with the Court's ruling on Defendants' Motion *in Limine* No. 7 (ECF No. 231), the Court will defer ruling on this prong of ECF No. 135 until the time of trial. *See* ECF No. 282 at PageID #: [98-100].

V. ECF No. 143 - Timothy A. Ulatowski, M.S.

Defendants have designated Ulatowski as a general expert to provide opinion testimony regarding the FDA regulatory scheme, including the FDA § 510(k) clearance process regarding the TVT-O (and other Ethicon devices that are not at issue in the case at bar). Defendants also intend to elicit from Ulatowski other opinions that touch on different aspects of FDA regulations. *See* General Expert Report (ECF No. 143-1). Plaintiff moves the Court to exclude the opinions and testimony of Ulatowski.[2]

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[2] Plaintiff's Motion *in Limine* No. 1 also requested the Court "prevent Ethicon from offering evidence or argument relating to the activities of FDA consistent with the *limine* orders in MDL No. 2327, on the basis that such evidence is inadmissible under Federal Rules of Evidence 402 and 403." ECF No. 240 at PageID #: 42989. The Court granted the Motion *in Limine*. *See* ECF No. 282 at PageID #: [10-11]. Plaintiff's Motion *in Limine* No. 2 entitled "Argument, Evidence, or Testimony That the TVT Product Line is Still on the Market" was also granted. *See* ECF No. 282 at PageID #: [11]. The Court, however, allowed counsel for the parties to file a post-hearing single

(continued...)

A.

Plaintiff argues Ulatowski is not qualified to offer opinions outside the context of the FDA regulatory process. According to Plaintiff, the Court should exclude any of his opinions as to the sufficiency of warnings, patient brochures, labeling, and manufacturing because Ulatowski's master's degree in physiology and bachelor's degree in microbiology do not qualify him to render an expert opinion on such issues – which are also solely within the province of the jury.

This prong of the motion seeking to exclude Ulatowski's opinions regarding manufacturing processes, the content of warnings or patient brochures is denied.

B.

Next, Plaintiff contends Ulatowski's FDA opinions are inadmissible because they misleadingly suggest that the TVT-O mesh was considered "safe" or otherwise "approved" by the FDA which, as explained below, is not the case for Class II medical devices like the TVT-O that are merely "cleared" through the 510(k) process. Plaintiff claims the FDA opinions of Defendants' expert are inadmissible because they have no probative value and carry a high risk of prejudice, confusion, and delay. *See* Fed. R. Evid. 403. According to Plaintiff, Ulatowski's § 510(k) clearance opinions are irrelevant under Fed. R. Evid. 402 and should be excluded because the 510(k) process has nothing to do with product safety.

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[2](...continued)
joint submission setting forth their follow-up arguments regarding Plaintiff's Motion *in Limine* No. 2. *See* ECF No. 293.

Under the Federal Food, Drug, and Cosmetic Act, a manufacturer seeking to market a new medical device may attempt to bypass the FDA's normal premarket approval process by submitting a "§ 510(k) notification." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996). "[T]he 510(k) process is focused on equivalence, not safety." *Eghnayem v. Boston Scientific Corp.*, 873 F.3d 1304, 1317 (11th Cir. 2017) (quoting *Lohr*, 518 U.S. at 493 (underlining in original)). "[T]he FDA completes the average 510k review within 20 hours, and the agency considers only whether the device is indeed the equivalent of a preexisting device—regardless of how unsafe or ineffective the grandfathered device happens to be." *Id.* at 1318 (quoting *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1369 n.1 (11th Cir. 1999)). Medical devices that enter the market through the § 510(k) process have "never been formally reviewed under the [Medical Device Amendments of 1976] for safety or efficacy." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) (quoting *Lohr*, 518 U.S. at 493). Rather, the § 510(k) exemption is "intended merely to give manufacturers the freedom to compete, to a limited degree, with and on the same terms as manufacturers of medical devices that existed prior to 1976." *Lohr*, 518 U.S. at 494.

C.

Plaintiff notes that Federal courts routinely exclude FDA opinions on the 510(k) clearance process, such as those offered by Ulatowski. In *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, 2014 WL 6680356 (S.D. W. Va. Nov. 25, 2014), the MDL court stated:

> . . . this court will not tolerate the presentation of evidence that touches on or in any way alludes to the 510(k) clearance process. Furthermore, insofar as Mr. Ulatowski's opinions relate to FDA regulations or procedures, FDA decision-making, FDA communications, or Ethicon's compliance with such, they are **EXCLUDED**. I have previously expressed concern with the risks of leading the jury into the confusing domain of the FDA.

* * *

> . . . I emphasized that "expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion . . . than enlightenment." *Id.* at *35. I have these same concerns about Mr. Ulatowski's opinions, which appear to entirely focus on FDA regulations, FDA procedures (the 510(k) clearance process as well as others), FDA communications, and Ethicon's compliance with FDA law. (*See* Ulatowski Report [Docket 202–4], at 6–38 (discussing FDA provisions "relevant to the subject case," in addition to other FDA requirements)). Thus, any opinion testimony on matters of the FDA is **EXCLUDED**, and the plaintiff's motion on this issue is **GRANTED**.

Id. at *10 (bold in original); *see also* *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1018 (7th Cir. 2020) (affirming exclusion of evidence of 510(k) clearance of Ethicon's Prolift mesh product); *Campbell v. Boston Scientific Corp.*, 882 F.3d 70, 77 (4th Cir. 2018) (same); *Eghnayem*, 873 F.3d at 1317 ("The district court also did not abuse its discretion when it excluded BSC's 510(k) evidence."); *Huskey v. Ethicon, Inc.*, 848 F.3d 151,160-61 (4th Cir. 2017) (same); *Cisson v. C.R. Bard, Inc.(In re C.R. Bard, Inc.)*, 810 F.3d 913, 921-22 (4th Cir. 2016) ("exclusion of the 510(k) compliance evidence was not improper"); *Foster v. Ethicon, Inc.*, 4:20-CV-04076-RAL, 2021 WL 4476642, at *5 (D.S.D. Sept. 30, 2021).

Defendants note that since the MDL court's ruling, the New Jersey Appellate Division considered the same arguments in another pelvic mesh case and held FDA 510(k) evidence is relevant and admissible, particularly as it relates to punitive damages. *See* *Hrymoc v. Ethicon, Inc.*, 467 N.J. Super. 42, 80 (App. Div. 2021) (reversing two trial courts' categorical exclusions of 510(k) evidence because a "complete ban on any disclosure of the 510(k) clearance process to the jurors . . . ha[s] the clear capacity to lead to possibly unjust results), *cert. granted*, 248 N.J. 564 (Oct. 22, 2021). In *Swintelski v. American Med. Sys.*, the district court stated in a summary ruling:

> AMS counters that it would be inherently unfair to allow Plaintiffs to introduce evidence and argument about AMS's purported failure to conduct clinical trials without permitting AMS to explain that FDA regulations do not require clinical trials for 510(k) devices such as the SPARC Mesh Sling 154. The Court agrees with Defendant. Plaintiffs sought the exclusion of evidence related to FDA's 510(k) clearance process. Now, after a ruling in its favor on that subject, Plaintiffs seek essentially to prevent Defendant from introducing evidence to explain the reason for the absence of clinical trials/studies.

No. 20-60410-CIV-CANNON/Hunt, 2021 WL 3674869 (S.D.Fla. Aug. 13, 2021).

D.

The Court finds Ulatowski is qualified to opine about matters outside of the FDA regulatory process, including whether Defendants provided a sufficient warning of adverse events. But, his FDA regulatory opinions, *inter alia*, concern the § 510(k) clearance process, which federal courts have routinely excluded. Accordingly, the Court grants ECF No. 143 in part and excludes at this time Ulatowski's opinions and testimony as to § 510(k) regulatory process. The within ruling, however, is not "meant to ban . . . all evidence of the FDA clearance process." ECF No. 282 at PageID #: [60].

IT IS SO ORDERED.

April 13, 2022
Date

/s/ Benita Y. Pearson
Benita Y. Pearson
United States District Judge